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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,446	01/08/2007	Sonia Amparo Ospina Sanchez	1556-0108PUS1	4158

2292 7590 12/09/2010

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EXAMINER
UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,446	OSPINA SANCHEZ ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-38 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *24-29,34-36 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 30-33, 37 and 40-42* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This Office Action is in response to the Applicant's reply received 9/27/10. Claims 23-38 and 40-42 are pending. Claims 24-29, 34-36, and 38 are withdrawn. Claims 1-22 and 39** are cancelled. Claims 23, 30-33, and 37 have been amended. Claims 40-42 are new. Claims 23, 30-33, 37, and 40-42 are considered in this Office Action.

**Claim 39 is mistyped as 49.

New Rejections Necessitated by Amendment

The recent amendments to the claims and arguments have overcome the previous rejections under 35 USC § 112 1st and 2nd paragraph but have invoked several others that are best addressed before responding to the arguments since they affect claim interpretation.

Claim Rejections - 35 USC § 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 30-33, 37, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears the Applicant wishes to use extracellular enzymes secreted by *Lactococcus lactis* NRRLB-30656 for the *in vitro* production of a biopolymer comprising a 0.2 to .07 glucose/fructose ratio that is 900-1100 kDa in weight and numerous other physical properties. However the claims do not reflect this.

In claims 23 the relationship between the *Lactococcus lactis* NRRLB-30656 metabolism products and the “enzyme extract or preparation having two types of glucosyltransferase and fructosyltransferase activity” remains is unclear. In particular it is not clearly understood if the glucosyltransferase and fructosyltransferase activity is directly from the *L. lactis* or has been added as part of the process of making the "enzymatic extract or preparation". Also it is unclear if the enzyme recovered in claim 23, step b) are the “metabolism products” or the "enzymatic extract or preparation" of subsequent step c). The term “metabolism products from *Lactococcus lactis* strain NRRLB-30656)” is unclear since it is unclear if these are molecules from the L. lactis itself (i.e. DNA, RNA, lipids) or molecules that were produced by the bacteria such as carbon dioxide from its respiration.

Claim 30 is unclear since it does not contain the entire *Lactococcus lactis*, but only its enzymatic extract or preparation. This is confusing since there is a fermentation step, which would require a whole, fully functioning microorganism. In this case the presence of the sucrose carbon source is confusing since it is unclear what component of the method utilizes this "carbon source" since fermentation cannot occur without a whole microorganism.

In claim 30, the glucosyltransferase and the fructosyltransferase activity is from the enzymatic extract or preparation of the *L. lactis*, but it is unclear what is the origin of the metabolism products. In particular it is unclear if the metabolism products are from the *whole L. Lactis* or they are simply from its enzymatic extract or preparation.

Claim 30 and claim 31 are indefinite for other reasons as well. In claim 30, the sucrose containing medium is a carbon source for the fermentation for the *L. lactis*, which as motioned above is not present in this method. The enzymatic extract has its own substrate in claim 30. However claim 31 depends from the method of claim 30 but now has the sucrose carbon source and a substrate for the enzyme. It is unclear if the sucrose is to be considered the “carbon source" for the enzyme. Furthermore this creates a confusing redundancy since the enzyme now has a "carbon source" and a substrate and it is unclear if these two are to be considered together are separately.

In claim 42 it is clear that the metabolism products are from the *L. lactis*, but again it is unclear if the "enzymatic extract or preparation” originated from the *L. lactis* as well.

Claims 23, 30-33, 37, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

The step in the method of making the biopolymer where the necessary glucose and fructose added.

This is a glucose/fructose biopolymer. However a step of adding a substrate (such as sucrose) with these sugars is not clearly defined in the claims but clearly required in the specification (see Example 3 part A). The specification does not provide any other method as to how the glucose and fructose can be produced for this

biopolymer. Therefore the critical step of adding these sugars to the production of the biopolymer is absent and a confusing gap in the claims exists.

While claim 30 does include that a sucrose containing medium is used for the carbon source for fermentation of the L. lactis, it is not clear that this sucrose is carried over to the preparation of the biopolymer via the enzyme extract.

Specification Objections

The Examiner has withdrawn the 35 U.S.C. 112 1st paragraph rejection for claims 23, 30-33 and 37, as failing to comply with the written description requirement since the Applicant pointed to their support in the originally filled claims. However, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification must be amended to contain the subject matter for biopolymer found in originally filed claims 3 and 4 submitted on 1/08/07.

Claim Objections

Claim 23 is objected to since the spelling of *Lactococcus lactis* NRRLB-30656 is not consistent throughout the claim.

Response to Applicant Arguments

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In the response submitted by the Applicant, the 35 U.S.C § 102/103 alternative rejection over Manaca De Nadra et al. are withdraw for the method claims 30 and 33 are withdrawn but were considered but not found persuasive for the composition claims 23 and 37.

Claims 23, 37 and new claims 40-43 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Manaca De Nadra et al. (Int. J. of Food Microbiology, 1995).

This claim is drawn to a glucose and fructose biopolymer having the following properties:

a) 0.2 to 0.7 glucose/fructose ratio;

b) 900-1,100 kDa molecular weight;

c) Two vitreous transition points, one between 20 ^{o}C and 30 ^{o}C and another between 190 ^{o}C and 220 ^{o}C;

d) Stability in aqueous solutions with a pH value from 2-9;

e) 1,000 to 3,000 centipoise viscosity when the biopolymer is at 10% to 20% concentration in an aqueous solution at 30 ^{o}C;

f) Non-hygroscopic; and

g) Highly soluble in water, able to form a hydrogel homogeneous dispersions at maximum concentration of 50% w/v.

As stated in the previous office action, the source of this biopolymer, *L. lactis* NRRLB-30656 enzyme extract or preparation is a product-by-process limitation and that is not provided significant patentable weight for a composition. MPEP 2113 is clear that the "patentability of a product does not depend on its method of production". Therefore art reading on the structure of the biopolymer will read on the claims.

Also claim 40 is an intended use for the biopolymer of 23. However intended uses are given little patentable weight since, as a composition, the invention is defined by its components and the limitations implied in the intended use are considered only if they impart a structural limitation (see M.P.E.P. § 2111.02 II). Claim 42 has the intended result that the biopolymer forms a hydrogel. Again, compositions are defined by their components. Therefor art reading physical characteristics such as the structure, will meet the limitations concerning the intended result of hydrogel formation since the physical makeup of the biopolymer is the same.

Manaca De Nadra et al. teach a biopolymer that has a glucose/fructose ratio calculated between 0.2 and 0.7 (Table 1, Glucose value divided by Fructose value) as a viscous agent in wine (pg 105). The log value of the molecular weight of their biopolymer is 6 (Fig 1, insert graph). This corresponds to a molecular weight of 1000 kDa. This biopolymer is water soluble (pg 105, last full paragraph) and stable in aqueous solutions at pH of 7 (pg 103, Section 2.5).

Manaca De Nadra et al. is silent as to characteristics c, e, f and g. However these are inherent characteristics of the structure of the polymer and are determined by experimentation. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' biopolymer differs, and if so to what extent, from the biopolymer discussed in Manaca de Nardra et al. The prior art biopolymer has the same structural limitations of glucose/fructose ratio, molecular weight and pH stability as the claimed biopolymer. The cited art taken as a whole demonstrates a reasonable probability that the biopolymer of the prior art is either identical or sufficiently similar to the claimed biopolymer and that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a prior art biopolymer is not disclosed in a reference does not make that biopolymer patentable. Applicants' biopolymer possesses inherent characteristics which might not be displayed in the tests used in Manaca de Nadra et al. Clear evidence that the biopolymer of the cited prior art does not possess a critical characteristic that is possessed by the claimed biopolymer (for example, a structural comparison or side-by-side comparison of characteristics c, e, f, and g) would advance prosecution and might permit allowance of claims to Applicants' biopolymer.

Manaca de Nadra et al. isolates their biopolymer using the following steps (pg 102, Section 2, Materials and Methods):

1) A preparation *Pediococcus pentosaceus* is fermented in MRS medium that comprising a sucrose (5 g/L) at pH ranging from 4.5 to 6.5 for 22 hours so the enzymes can produce the biopolymer;

2) The cells are centrifuged and removed from the supernatant;

3) The biopolymer is precipitated with three volumes of absolute ethanol;

4) This biopolymer precipitate was centrifuged again and the supernatant removed;

5) The biopolymer precipitate was dried at 37 ^{o}C;

6) The biopolymer was redissoved in distilled water to obtain a stock solution;

7) The biopolymer was further purified by either paper chromatography or ultrafiltration on a Sepharose column.

Therefore claims 23, 37 and new claims 40-42 are either anticipated or obvious in view of the above references.

Response to Applicant's Arguments

The Applicant argues that the biopolymer production is different and therefore free of the art of Manaca de Nadra et al. While this is sufficient to remove the rejection based on the method claims 30 and 33, this is not sufficient to remove the rejection over the composition claims where product-by-process limitations are given little patentable

weight. Therefore since the Manaca de Nadra et al. has a reasonably close chemical structure to the claimed biopolymer, the rejection remains.

The Applicant argues that the biopolymer is different from that of Manaca de Nadra et al. Specifically the Applicant argues that the biopolymer of Manaca de Nadra et al. contains hexose, galactose as well as glucose and fructose. However this argument is not convincing since the claims do not exclude the presence of other sugars such as hexose or galactose. Therefore the open language of "comprising" in the claims allows the inclusion of other sugars provided the glucose/fructose ration is the same of the biopolymer.

The Applicant argues that the claimed biopolymer "is entirely stable to strong acids and strong bases" unlike the biopolymer of Manaca de Nadra et al. which is hydrolyzed at 4N HCl. However this argument is not commensurate in scope with the claims. The claims only require pH stability from 2-9. Using the typical strong acid pH calculation ($pH=-\log[H^+]$), the pH of a 4N HCl solution is -0.6, which is far beyond the pH range specified in the claims. Indeed there is no proof in the Applicant's specification that it will not hydrolyze in a 4N HCl solution.

The Applicant's arguments that the claimed biopolymer is useful in functional nutrition is not commensurate with the scope of the claims. The claims are to a composition, therefore patentability relies heavily on the structure of the biopolymer and not its intended use.

Therefore the rejection of claims 23, 37 and new claims 40-42 stands.

Claims 30-33 are free of the art, while still being rejected over 35 U.S.C. 112.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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